K112480

DEC 13 2011

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

**Applicant**: Global Care Quest
2151 E. Grand Ave
El Segundo, CA 90245
(424) 218-8379

**Contact**: Winkie Wong
Associate Regulatory Affairs Specialist

**Device Identification**:

Common Name: Soft-copy reading system

Trade Name: (optional) VIEW1 Imaging

**Indications**: VIEW1 Imaging is a software that receives digital images and data from existing imaging equipment using DICOM 3.0 communication protocols and is not recommended for primary diagnosis. Images and data are stored on the server in deflate image and JPEG.

VIEW1 Imaging is designed to serve as an accessory to a Picture Archiving and Communication System (PACS). It is used with general purpose computing hardware for the display of medical image data as well as patient information. It is designed to provide storage, routing and display of DICOM image data through an executable program as well as in a web based format.

VIEW1 Imaging is intended for use as a tool by trained professionals such as physicians and must not be reviewed for primary image interpretations of Mammography images.

**Device Description**: VIEW1 Imaging uses three different interfaces: HL7, DICOM and Image Generator to present, transmit and stored clinical data and digital images to physicians to be used as a review tool. It also allow physicians to access these data and images via any standard web browser-based devices.

**Substantial Equivalence**: VIEW1 Imaging is substantially equivalent to IMCO-STAT (K063392). Both devices share the same indications for use and fundamental technologies, which is using DICOM 3.0 communication protocols and are able to store images in JPEG format. Both systems have the capability to provide mobile access to the information stored in the system.

The differences between the subject and predicate device are that the subject device also offers image compression into Deflate format, not just JPEG and it does not offer annotation or comparison of images that the predicate device offers.

**Conclusion:** VIEW1 Imaging is substantially equivalent to the identified predicate device and the minor differences between the subject and the predicate device do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Winkie Wong
Associate Regulatory Affairs Specialist
KARL STORZ Endoscopy America, Inc.
2151 E. Grand Avenue
EL SEGUNDO CA 90245

DEC 13 2011

Re: K112480
Trade/Device Name: VIEW1 Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 7, 2011
Received: December 8, 2011

Dear Ms. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

**Indication for Use**

**510(k) Number (if known):** Not yet assigned

**Device Name:** VIEW1 Imaging

**Indication for use:** VIEW1 Imaging consists of software that receives digital images and data from existing imaging equipments using DICOM 3.0 communication protocols. Images and data are stored on the server in deflate compressed image and proprietary header formats. The algorithms used to create compressed images follow known and accepted protocols, such as JPEG.

VIEW1 Imaging is designed to serve as an accessory to a Picture Archiving and Communication System (PACS). It is used with general purpose computing hardware for the display of medical image data and patient information. It is designed to provide storage, routing and display of DICOM image data through an executable application as well as in a web based format.

VIEW1 Imaging is intended for use as review tool by trained professionals, such as physicians, and must not be reviewed for primary image interpretations.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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